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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/699,175

10/31/2003

John R. Bianchi

4002-3441

1020

30565

7590

08/11/2004

WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP  
BANK ONE CENTER/TOWER  
111 MONUMENT CIRCLE, SUITE 3700  
INDIANAPOLIS, IN 46204-5137

EXAMINER

JACKSON, SUZETTE JAMIE

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

YW

<b>Office Action Summary</b>	<b>Application No.</b> 10/699,175	<b>Applicant(s)</b> BIANCHI ET AL.	
	<b>Examiner</b> Suzette J Jackson	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 72-133 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 72-133 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                              |                                                                                         |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/22/04</u> . | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of 7/12/04 in the reply filed on 7/12/04 is acknowledged. Applicant elects Species A Figures 4-16 and 35-39.

### ***Specification***

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: There is no antecedent basis for claims 72-133 specifically the limitation "*....less than approximately one-half of the width of the adjacent vertebral bodies*"

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 72-133 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular in claims 72, 91 and 111 applicant claims the limitations of "...*opposed upper and lower portions between said leading and trailing ends adapted to be placed at least in part.....said upper and lower portions being non-arcuate along at least a portin of the length of the implant....*" The opposed upper and lower surfaces of applicants implants are not non-arcuate. Further applicant claims a range of "...*less than approximately one-half of the width of the adjacent vertebral bodies*" and this range constitutes new matter.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 72-133 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. The phrase "...upper and lower portions being non-arcuate along at least a portion of the length of the implant" in claim 72, 91 and 111 is a relative phrase which renders the claim indefinite. The phrase is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree;

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and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In particular there is a leading end and a trailing end, an upper opposed portion and a lower opposed portion. The upper opposed portion and a lower opposed portion are arcuate along the length of the spacer.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 72, 91 and 111 are rejected under 35 U.S.C. 102(e) as being anticipated by Pafford et al. 6,371,988. Pafford et al. discloses the invention as *claimed noting figures 7, 24 and 47-49 and as best interpreted* comprising:

An interbody spinal implant (40) made of cortical bone (col. 6, lines 43-48) for insertion at least in part into an implantation space formed across the height of a disc space between adjacent vertebral bodies of a human spine, the vertebral bodies having an anterior aspect and a posterior aspect comprising:

a leading end (48) , a trailing end (26') opposite the leading end, wherein the implant has a length along a mid-longitudinal axis of said implant from the

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leading end to the trailing end; opposed upper and lower portions (*the upper portion is the tooled beveled space shown in figures 47-49 and the lower is interpreted as opposite of the beveled end*) between the leading and trailing ends said upper and lower portion being non-arcuate along at least a portion of the length of the implant (*the tooled beveled portion is flat and non-arcuate*); an interior facing side, an exterior facing side opposite the interior side, and a maximum width there between capable of being less than approximately one-half of the width of the adjacent vertebral bodies (see fig. 24 interior side is right and exterior side is left); said interior and exterior sides connecting the upper and lower portions and said leading and trailing end, said leading end having a generally straight portion (straight slot including hole 49 for tool) from side to side, said interior side (*see fig. 24 where interior side of one of the implants is to the right*) forming a corner (*the tooled bevel side and the straight slot for the tool form this corner*) with said generally straight portion of the leading end; said implant being manufactured from a bone ring obtained from a major long bone of a human having a medullary canal.

### **Conclusion**

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Shimp et al. 6,706,067 ; Pafford et al. 6,371,988 ; Michelson 6,350,283 ; McKay 6,270,528 ; Coates et al. 5,989,289 ; Branch et al. 2004/0093083 ; Michelson 2002/0161442 all show related material.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 703-308-6516.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

A handwritten signature in black ink, appearing to read 'Suzette J. Jackson', with a stylized flourish at the end.

Suzette J. Jackson  
04 August 2004